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Treatment and Induced Menopause

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Introduction

This is the first annual report for the Clinical Nurse Research Award: Relationship of Neurocognitive Function (NCF) to Breast Cancer Treatment and Induced Menopause. The grant has a training component and a research component. The training component includes formal and informal experiences related to NCF, cancer research, and research methodology. The research component includes the design and execution of a nine-month, longitudinal, repeated measures, descriptive study of NCF in a group of women receiving chemotherapy for breast cancer. To clarify the role of induced menopause in the experience of NCF, the subjects will be compared to a group experiencing surgically induced menopause.

Body

The study has been designed. A clinical site has been chosen and negotiations with that site have been successfully concluded. A research assistant has been hired and begun training. The Human Subjects review by appropriate Institutional Review Boards is underway. The very slow IRB process has delayed beginning subject recruitment and data collection.

Technical Difficulties and Variance from Original Statement of Work

Due to lack of clarity about timing of the research project, I have postponed coursework to this coming academic year. As soon as the grant was funded in May, 2004, I began receiving requests from the DOD to submit human subjects materials as soon as possible. I had expected to design the study based on what I had learned in the coursework. Because I understood that I was expected to begin data collection during the first year of the grant, I prioritized research activities, and postponed coursework. I completed designing the study, formalizing the protocol and obtaining a clinical site for data collection. I submitted documents for Human Subjects review. I expected to be in data collection late in 2004 or early in 2005.

I have experienced substantial delays in hearing from each of the Institutional Review Boards for this study. I received approval from the clinical site on 8/30/2004. Expedited approval from the University of Connecticut came on 11/17/2004 but was backdated to be consistent with the clinical site date of 8/30/2004. I sent protocols via the CDMRP website on 12/6/2004. I received request for revisions on 5/2/2005. After these revisions are accepted, I will need to resubmit to the IRBs at the clinical site and the university, both because of the need to make revisions based on the revisions requested by the DOD and because the original IRB approvals will expire shortly.

Key Research Accomplishments

Attend appropriate research conferences.

- Attended 8th National Cancer Nursing Research Conference, Oncology Nursing Society. Presentations about analysis of longitudinal data were particularly useful for my work.
- Attended 17th Annual Scientific Sessions of the Eastern Nursing Research Society. Heard several presentations related to cancer research and its methodological issues. Presented research on older women with breast cancer.

- Attended Association of Women's Health, Obstetric and Neonatal Nurses Annual Convention. Presented research on racial disparities in breast cancer.

Throughout the entire training program, identify and attend grand rounds, colloquia, and journal clubs that address topics related to breast cancer research.

- Met with mentor, Dr. Ruth McCorkle, at Yale School of Nursing.
- Attended post-doctoral research meetings at Yale.
- Attended monthly meetings with breast cancer researchers in basic and clinical sciences at the University of Connecticut Cancer Center.
- Joined Advanced Nursing Research Special Interest Group, Oncology Nursing Society

Attend DOD BRCP research dissemination meeting

- Scheduled for June, 2005.

Interview research assistants; Recruit and train the research assistants

- Hired Joyce Thielen, MS, RN, doctoral student to be research assistant. Training ongoing.

Solidify liaisons with clinical sites for data collection

- Successfully negotiated to establish plan for data collection at D'Amour Cancer Center, Baystate Medical Center, Springfield, MA.
- Began inquiries at the University of Connecticut Health Center.

Select appropriate measures

- Instruments selected and obtained from vendors.

Finalize design of the research protocol

- Will collect initial data at or before first chemotherapy treatment or before hysterectomy. Subsequent data will be collected at two, six and nine months following initial data.

Determine appropriate number of subjects (estimate 40)

- Based on consultation with statistician, recruitment goals are 25 breast cancer patients and 25 hysterectomy patients.
- Developed plan for accrual and retention of subjects.

Obtain human subjects approval

- Obtained human subjects approval from Baystate Medical Center and the University of Connecticut
- Submitted human subjects materials to DOD. Revisions are pending.

Reportable Outcomes

Presentations

- Researching Symptom Experience Following Surgical Treatment of Breast Cancer, University of Connecticut Health Center, May 19, 2005.
- Patterns of Symptom Distress in Elderly Women with Breast Cancer. Poster, Distinguished Scholars Day, University of Connecticut, April 14, 2005
- Patterns of Symptom Distress in Elderly Women with Breast Cancer. Paper, 17th Annual Scientific Sessions of the Eastern Nursing Research Society, April 8, 2005.
- Relationship of Neurocognitive Function to Breast Cancer Treatment and Induced Menopause, University of Connecticut Health Center, December 16, 2004
- Relationship of Neurocognitive Function to Breast Cancer Treatment and Induced Menopause, University of Connecticut School of Nursing Advisory Board and UConn Foundation, October 1, 2004.
- Questioning the Information on Delay and Racial Disparities in Breast Cancer Survival, Paper, Association of Womens Health, Obstetric and Neonatal Nurses Annual Convention, "Challenging the Status Quo", June 29, 2004.

Manuscripts

- Patterns of Symptom Distress in Older Women after Treatment for Breast Cancer (under review)

Employment or research opportunities applied for and/or received based on experience/training supported by this award.

- Promoted to Associate Professor, granted tenure at University of Connecticut School of Nursing
- Member, Breast Cancer Research Cooperative, University of Connecticut Cancer Center

Conclusions

This award builds on the grantee's extensive clinical background in women's health and primary care by facilitating the transition from geriatric research to breast cancer research. The grant has a training component which includes formal and informal experiences related to NCF, cancer research and research methodology, and a research component which includes the design and execution of a nine-month longitudinal, repeated measures, descriptive study of NCF in a group of women receiving chemotherapy for breast cancer. To clarify the role of induced menopause in NCF, the subjects will be compared to a group experiencing surgically induced menopause.

Research project activities have been prioritized. The study has been designed, a clinical site has been chosen and negotiations with that site have been successfully concluded. A research assistant has been hired and begun training. The very slow human subjects review process has delayed beginning subject recruitment and data collection. Once the human subjects review process is complete, subject accrual and data collection will begin.

Formal coursework will take place in year two. Training activities have included attending conferences and interdisciplinary meetings, presenting research, writing papers based on research done with the mentor and reading

materials related to the design and management of longitudinal research and clinical trials, particularly in cancer.

References

None

Appendices

None